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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/640,218	08/16/2000	Miroslav Colic	4904-4	3341

7590

05/08/2002

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EXAMINER

WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 05/08/2002

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/640,218

Applicant(s)

COLIC, MIROSLAV

Examiner

Joseph Weitach

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-14 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Application/Control Number: 09/640,218

Page 2

Art Unit: 1632

DETAILED ACTION

This is an original application filed August 16, 2000, which claims benefit to provisional application 60/149,131, filed August 16, 1999.

Upon reconsideration of the restriction requirement, the previous restriction requirement is vacated in favor of the restriction requirement set forth below. Specifically, in claim 5 a silica containing solid is also defined as a silica gel, absent other components.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 2, 9 and 10, drawn to pharmaceutical composition comprising a silica containing solid, classified in class 424, subclass 400, class 106, subclass 287.34.
- II. Claims 3 and 4, drawn to pharmaceutical composition comprising a zeolite encapsulated metal or metal complex, classified in class 502, subclass 60.
- III. Claim 5, drawn to pharmaceutical composition comprising a silica gel or other silicas containing encapsulated metals, classified in class 516, subclass 98, class 428, subclass 546.

Art Unit: 1632

- IV. Claim 5, drawn to pharmaceutical composition comprising a silica gel or other silicas containing proteins, classified in class 516, subclass 98, class 530, subclass 300.
- V. Claim 5, drawn to pharmaceutical composition comprising a silica gel or other silicas containing DNA, classified in class 516, subclass 98, class 536, subclass 23.1.
- VI. Claim 5, drawn to pharmaceutical composition comprising a silica gel or other silicas containing whole cells, classified in class 516, subclass 98, class 435, subclass 325.
- VII. Claim 5, drawn to pharmaceutical composition comprising a silica gel or other silicas containing tissue, classified in class 516, subclass 98, class 435, subclass 1.1.
- VIII. Claim 6, drawn to pharmaceutical composition comprising a mesoporous aluminosilicate containing encapsulated metals, classified in class 516, subclass 98, class 428, subclass 546.
- IX. Claim 6, drawn to pharmaceutical composition a mesoporous aluminosilicate containing proteins, classified in class 516, subclass 98, class 530, subclass 300.
- X. Claim 6, drawn to pharmaceutical composition comprising a mesoporous aluminosilicate containing DNA, classified in class 516, subclass 98, class 536, subclass 23.1.

Art Unit: 1632

- XI. Claim 6, drawn to pharmaceutical composition comprising a silica gel or other silicas containing small molecules, classified in class 516, subclass 98, and various classes depending on the nature of the small molecule.
- XII. Claims 7 and 8, drawn to pharmaceutical composition comprising a silica containing solid modified by surface absorption of molecules, classified in class 516, subclass 98, and various classes depending on the nature of the molecules used in the absorption.
- XIII. Claim 11, drawn to a method of modifying gene expression by administration of a composition of silica and antioxidant or oxidant, unclassified because there is no specific classification for a general oxidant or antioxidant and encompasses only intended use of specific compounds.
- XIV. Claim 12, drawn to method of enhancing immunogenicity of biological macromolecule, cells or cell fragments comprising administering a silica containing biological macromolecule, cells or cell fragments, classified in class 424, subclass 93.21, class 514, subclass 44, class 530, subclass 350.
- XV. Claims 13 and 14, drawn to method of providing sustained deliver of a pharmaceutically active agent comprising by administration of a composition of silica and the pharmaceutical agent; unclassified because there is no specific classification for a general pharmaceutical agent and encompasses only intended use of specific compounds.

Art Unit: 1632

The inventions are distinct, each from the other because of the following reasons:

Inventions I-XII are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the silica containing solid alone can be used in the pharmaceutical composition. The silica can be derived from zeolites, silicas, clays or double hydroxides (claim 2) and can be modified to affect the physical property of the silica. The subcombination has separate utility such as silica gels containing metals, proteins, DNA or cells, because each would have properties different from the silica containing solid alone and different properties from each other. Metals, proteins, DNA and cells represent unique compositions each with unique and different physical properties which would not be obvious over the other.

Groups I-XII and XIII-V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case gene expression can be modified by administration of antisense oligonucleotides (method encompassed by group XIII), immunogenicity can be enhanced by delivery of an antigen in an adjuvant (method encompassed by group XIV), and sustained

Art Unit: 1632

delivery of an agent can be accomplished by use of other depot formulations (method encompassed by group XV). Further, the product of Group I is routinely present in cosmetics for non-pharmaceutical purposes.

Groups XIII-XV are drawn to different and distinct methods. The methods of groups II-IV each use different compositions and would require different and unique preparations and steps to practice the claimed methods.

The inventions above are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each of the above invention is not co-extensive particularly with regard to the literature search. Further, a reference which would anticipate the invention of any one Group would not necessarily anticipate or make obvious any of the other groups.

For these reasons restriction for examination is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Voitach whose telephone number is (703)305-3732.

Art Unit: 1632

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (703)305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist Pauline Farrier whose telephone number is (703)305-3550.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703)308-4242 and (703)305-3014.

Joseph T. Waitach

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AU 1632